

REMARKS

Applicant submits this Amendment in reply to the Office Action mailed December 4, 2009.

By this Amendment, Applicant amends claim 16 and adds new claims 28-33. The originally filed specification, drawings, and claims fully support the subject matter of amended claim 16 and new claims 28-33.

Before entry of the Amendment, claims 1, 3-6, 8, 9, and 11-18 were pending in this application. After entry of this Amendment, claims 1, 3-6, 8, 9, 11-18, and 28-33 are pending in this application. Claims 1, 16, and 30 are the sole independent claims.

On page 2 of the Office Action, claim 16 was rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. In particular, the Office Action asserts that the limitation "wherein the electrode" recited in claim 16 lacks sufficient antecedent basis. Applicant has amended claim 16 to provide antecedent basis for the claimed electrode, solely in order to expedite the prosecution of this case. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the Section 112, second paragraph, rejection.

On page 2 of the Office Action, claims 1, 3-5, 8, 9, and 11-18 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,607,389 to Edwards et al. ("Edwards"). Applicant traverses this rejection.

A proper anticipation rejection requires each and every element set forth in the claim to be found in a single prior art reference. MPEP § 2131. Edwards does not disclose each and every feature of the claimed invention. For example, independent claim 1 recites a biopsy system comprising, among other aspects, a first placeholder

element and "a handle including a channel extending therethrough for receiving the first placeholder element . . . the handle being removably coupled to the first placeholder element so that the first placeholder element may be left in [a] first selected location [in a patient's body]."

Pages 2 and 3 of the Office Action asserts that, with respect to Edwards, torque tube 312 corresponds to the claimed first placeholder element, and upper and lower handle plates 276, 300, collectively, correspond to the claimed handle. Further, the Office Action cites Fig. 6 of Edwards, to support the Examiner's contention that upper and lower handle plates 276, 300 are removably coupled to torque tube 312. See page 3 of the Office Action. Applicant respectfully disagrees. Figure 6 of Edwards "is an exploded view of the RF ablation catheter shown in FIG. 1." See col. 5, lines 27-28 of Edwards. That is, Figure 6 shows a diagrammatic representation of the internal components of the ablation catheter device, and does not necessarily disclose that handle plates 276, 300 of handle 4 are removably coupled to torque tube 312. Furthermore, nothing in the disclosure of Edwards, with regard to Figure 6 or elsewhere, teaches or suggests that handle plates 276, 300 of handle are "removably coupled to" torque tube 312. Instead, to the contrary, Edwards teaches that torque tube 312 extends distally from torque coupler 314 which is mounted in the distal end of the housing of handle 4 of the catheter device. See col. 9, lines 9-10 and 13-14 of Edwards. And, col. 10, lines 58-61, of Edwards expressly discloses that, in operation, following tissue resection "stylet 1102 [is] withdrawn into the sleeve 1104, the sleeve 1104 withdrawn into the catheter, and the catheter completely withdrawn from the body," in stark contrast to claimed subject matter of independent claim 1.

In the event the Examiner maintains that handle plates 276, 300 are indeed “removably coupled” to the tube 312 because handle plates 276, 300 may be separated from one another and torque tube 312 without regard to the disclosed functionality of the Edwards device, Applicant submits that such reasoning and interpretation of Edwards is inappropriate. Separating handle plates 276, 300 from one another and torque tube 312 would be undesirable since it could destroy the functionality of the Edwards device. In particular, Edwards teaches that electrode control slides 10, 11 and sleeve control slides 12, 13 are attached through outer slots 278, 280, 286, 288 in upper handle plate 276 to slide blocks 282, 284, 290, and 292, respectively. See col. 8, lines 52-58 of Edwards. Sleeves and electrodes of stylets 8 are in turn secured to the sleeve slide blocks to effectuate movement of the sleeves and electrodes relative to the catheter device. See col. 9, lines 38-44 and 47-51 of Edwards. To remove handle plates 276, 300 from one another and from the remainder of the catheter would destroy the attachment of the control slides 10, 11, 12, and 13 to the sleeves and electrodes of stylets 8 and the intended functionality of the Edwards device.

Accordingly, Applicant submits independent claim 1 is allowable for at least these reasons.

In another example, Edwards fails to disclose each and every feature of independent claim 16. Independent claim 16 recites a biopsy system comprising, among other aspects, “a tissue treatment element insertable to the first selected location through the first element guide, the tissue treatment element being insertable through the first element guide after the first placeholder element has been separated

from the handle, wherein the tissue treatment element comprises an electrode, and wherein the electrode is a multi-barbed electrode."

In formulating the rejection of independent claim 16, pages 4 and 5 of the Office Action assert that torque tube 312 of Edwards corresponds to the claimed placeholder element, upper and lower handle plates 276, 300, collectively, correspond to the claimed handle, and electrical receptor 294 corresponds to the claimed tissue treatment element. Electrical receptor 294 cannot be inserted into a lumen of torque tube 312, at least because of the size, shape, and functionality of receptor 294. Indeed, Edwards explicitly teaches that "electrical receptor 294 is received in respective cavities 296 and 298 in the respective upper handle plate 276 and lower handle plate 300 attached thereto." See col. 8, lines 61-62 of Edwards. Thus electrical receptor 294 cannot correspond to the claimed tissue treatment element since claim 16 expressly requires the tissue treatment device be "insertable to the first selected location through the first element guide."

Moreover, even assuming, for arguments sake, that electrodes 442 and 444 could be construed to correspond to the first tissue treatment element, which Applicant does not necessarily concede, Edwards would still be a deficient reference. Claim 16 recites "tissue treatment element includes an electrode, and wherein the electrode is a multi-barbed electrode." Electrodes 442 and 444 together do not constitute a multi-barbed electrode, as asserted on page 5 of the Office Action, because each electrode 442 and 444 is individually operated. See col. 9, lines 36-53 of Edwards. Further, Edwards fails to disclose, teach, or otherwise suggest that either electrode 442 or 444 is

itself a multi-barbed electrode. Accordingly, Edwards fails to disclose each and every aspect of claim 16.

Applicant submits independent claim 16 is allowable for at least these reasons.

Further, rejected claims 3-6, 8, 9, and 11-15, 17-18, and 28-29 depend directly or indirectly from one of independent claims 1 and 16 and are therefore allowable for at least the same reasons as their respective independent claims are allowable as well as for their additional features.

On page 5 of the Office Action, claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Edwards in view of U.S. Patent No. 6,213,957 to Milliman et al. ("Milliman"). Even if Milliman teaches what the Examiner alleges, which Applicant does not concede, Milliman fails to overcome the aforementioned deficiencies of Edwards. Claim 6 therefore is at least allowable due to its dependence on claim 1. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the Section 103(a) rejection of claim 6 based on Edwards and Milliman.

Insofar as Edwards may be applied to new claims 28-33, Applicant submits these claims are patentable over Edwards for a number of reasons. For example, new dependent claim 28 recites "wherein the handle includes a fitting projecting distally therefrom configured to be received in a correspondingly shaped fitting on a proximal end of the first placeholder element." As alluded to above, the Office Action alleges that handle plates 276, 300, collectively, correspond to the claimed handle. As clearly shown in, for example, Figure 6 of Edwards, plates 276, 300, alone or together, do not include "a fitting projecting distally therefrom," as required by claim 28. Moreover, in the event the Office Action takes the position that tension assembly 308 corresponds to the

claimed fitting, Applicant submits tension assembly 308 is configured to receive torque tube 312. See col. 9, lines 13-14 of Edwards. No portion of tension assembly 308 is "configured to be received in a correspondingly shaped fitting on a proximal end" of torque tube 312.

New independent claim 30 recites a biopsy system comprising, among other aspects, "a handle including a channel extending therethrough for directing elements inserted into a proximal opening of the handle to the first lumen of the placeholder element, the handle being removably coupled to the first placeholder element so that the first placeholder element may be left in the first selected location; [and] a tissue sampling element insertable through the proximal opening of the handle and the first lumen for obtaining a sample of tissue from the first selected location, the tissue sampling element being removable from the proximal opening of the handle while leaving the first placeholder element at the first selected location." For at least the reasons discussed in greater detail above, Edwards does not disclose recitations of new independent claim 30. Additionally, Edwards fails to disclose "a tissue sampling element received in or removable from a proximal end of the handle," as recited in new independent claim 30. In the Office Action, the Examiner asserts that stylet guide corresponds to the claimed tissue sampling element. Stylet guide 6, however, is fixedly formed in the tip of catheter. See col. 7, lines 30-31 of Edwards. Thus stylet guide 6 cannot correspond to the claimed tissue sampling element as claim 30 recites a tissue sampling element being "insertable through the proximal opening of the handle . . . and removable from the proximal opening of the handle." In the event the Office Action takes the position that the biopsy sample stylet shown in, for example, Fig. 11

corresponds to the claimed tissue sampling element, Edwards discloses that a proximal end of a biopsy sample stylet is secured to the inner surface of a slide block in handle 4, similar to the electrode of Figs. 1, 6, and 9. See col. 10, lines 40-43 and 51-53 of Edwards. Accordingly, biopsy sample stylet also cannot correspond to the claimed tissue sampling element. Applicant notes that new dependent claims 31-33 depend from new independent claim 30, and are allowable due to their dependence from base claim 30.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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